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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|------------------------|------------------|
| 10/597,502 | 07/27/2006 | Marc Bohner | LUS-16768 | 2019 |
| 40854 | 7590 | 02/27/2009 | EXAMINER | |
| RANKIN, HILL & CLARK LLP | | | MERENE, JAN CHRISTOP L | |
| 38210 Glenn Avenue | | | | |
| WILLOUGHBY, OH 44094-7808 | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/27/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/597,502 | BOHNER ET AL. |
| | Examiner | Art Unit |
| | JAN CHRISTOPHER MERENE | 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 December 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-7,9,10 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5-7,9,10 and 13-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. **Claims 1, 5-7, 9-10, 13-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney US 4,220,151.

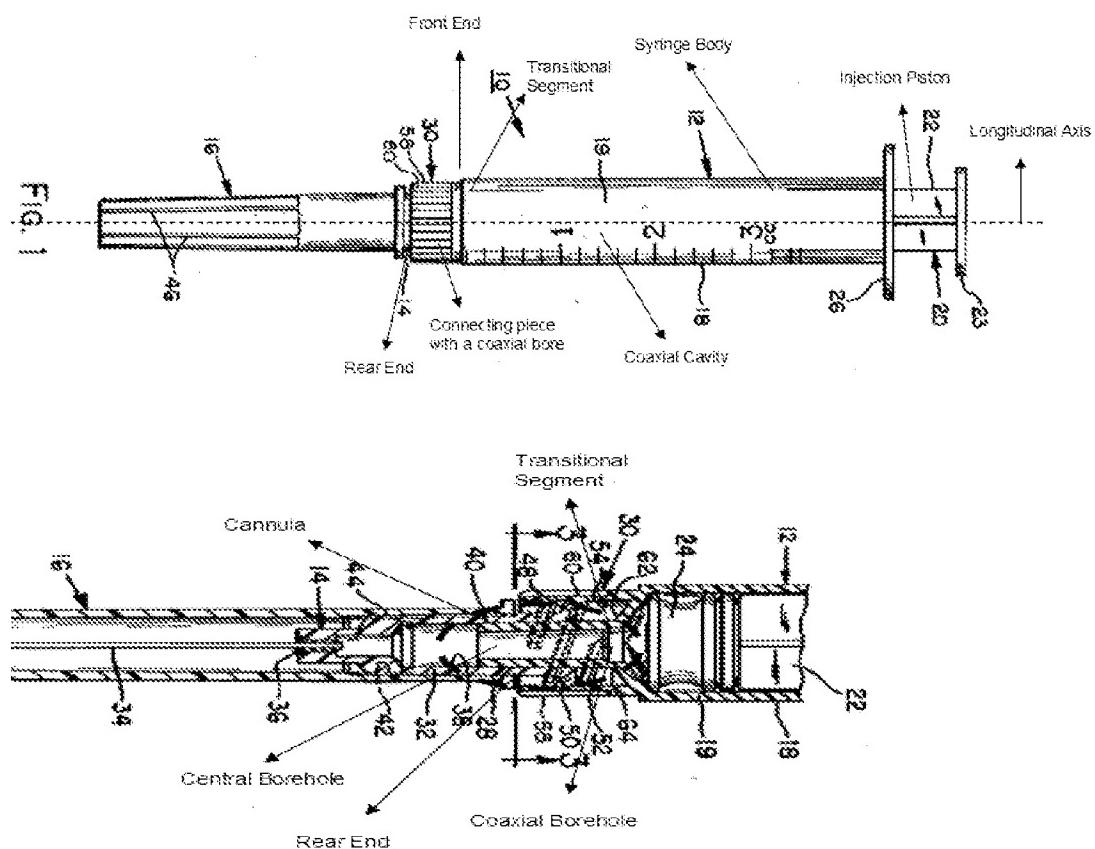
Regarding **Claim 1**, Whitney discloses an injection device especially for bone cement, comprising: A) a syringe body with a longitudinal axis, a front end, a connecting piece, disposed at the front end and having a coaxial borehole, and a coaxial cavity; B) an injection piston, which can be shifted coaxially in the cavity; and C) a cannula, which can be connected with the connecting piece, with a central borehole and rear end; wherein

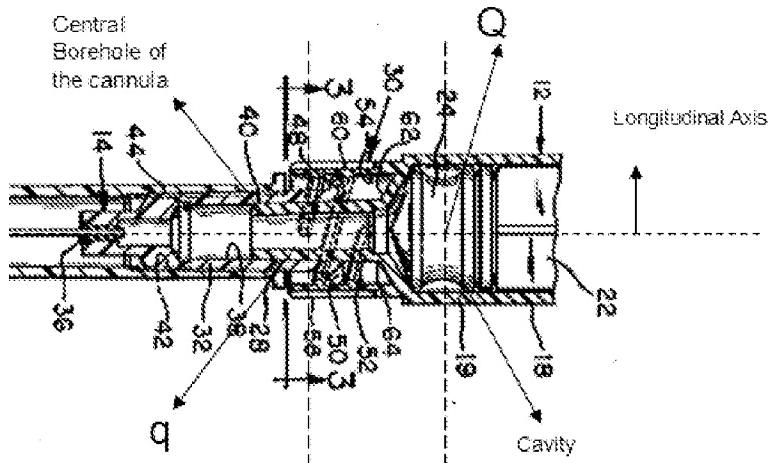
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D) the front end of the syringe body has a transition segment with a coaxial borehole with constant diameter, connecting the cavity with the borehole in the connecting piece; and wherein

E) the borehole in the transition segment and the central borehole have the same cross-sectional area orthogonal to the longitudinal axis at least at the rear end of the cannula;

F) the central borehole of the cannula has a constant cross-sectional area q in the axial direction (as seen in Figs below and see also Fig 4, where the transitional segment has a borehole with a constant diameter that is the same as the bore hole of the connecting piece).





Whitey also teaches:

in **Claim 5**, the borehole has an internal thread (#52) in the connecting piece (see Col 2 lines 66-67 and Figs in Claim 1);
in **Claims 6-7, 10**, means for screwing the cannula into the internal thread, where the means is an external thread (#50 see Col 2 lines 66-67, Col 3 lines 1-2)
complementary to the internal thread and means for screwing into the internal thread are constructed as a luer lock (see Col 2 lines 66-67 - Col 3 lines 1-2);

in **Claim 9**, the diameter of the borehole in the transition segment and the geometry of the internal thread in the connecting piece correspond to those of a luer lock connection (as seen in Figs above in Claim 1 and see Col 2 lines 66-67 - Col 3 lines 1-2);

in **Claims 13-14**, the diameter of the borehole in the transition segment and the geometry of the internal thread in the connecting piece correspond to those of a luer lock connection (as seen in Figs above in Claim 1 and see Col 2 lines 66-67 - Col 3 lines 1-2);

in **Claims 15-16**, the means for screwing into the internal thread are constructed as a luer lock adapter (as seen in Figs above in Claim 1 and see Col 2 lines 66-67 - Col 3 lines 1-2).

Whitey discloses the central borehole of the cannula has a constant cross sectional area q in the axial direction and the cavity of the body has a cross-sectional area Q as shown in the Figure in Claim 2, but does not explicitly disclose the ratio of the cross sectional areas q:Q is between 0.2 and 0.033.

However, it is clear that from the Figs that q has a smaller cross sectional area than Q, where it would be obvious that the ration between q:Q can be between 0.2 and .033.

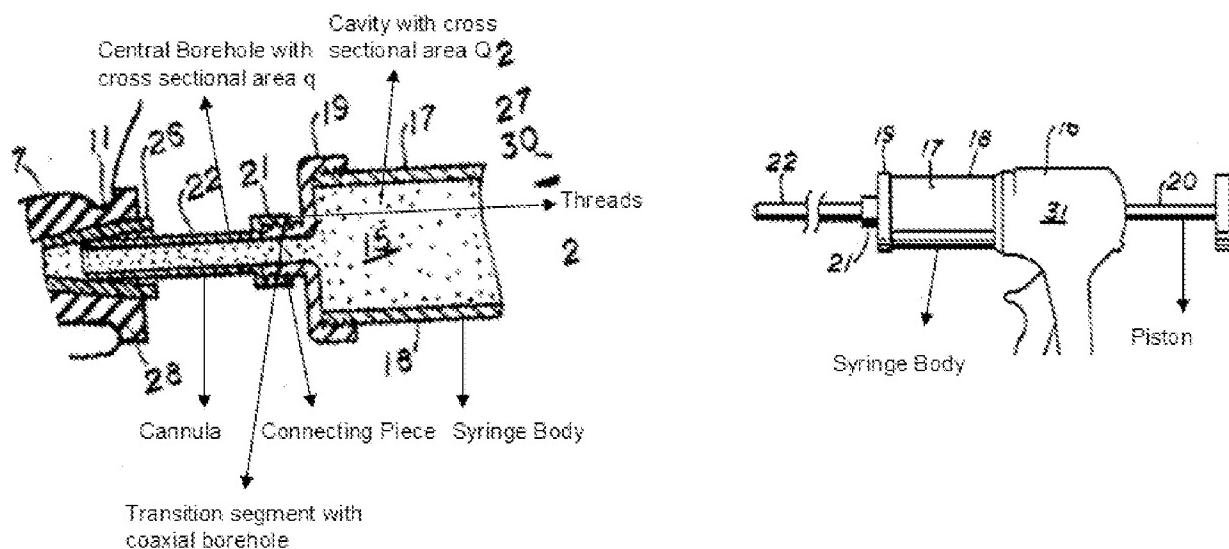
Nevertheless, it would also have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the cross sectional areas q:Q to be between 0.2 and 0.033, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

(The examiner further notes that the ration between q and Q refers to a change of size, where one of ordinary skill in the art would recognize the need to have different sizes to accommodate different patients and patient need. It would also have been an obvious matter of design choice to have the ratio between q and Q to be 0.2 and 0.033, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of

ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955) and see Response to Arguments below)

4. **Claim 1** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dozier US 4,815,454.

Regarding **Claim 1**, Dozier discloses an injection device especially for bone cement, comprising: A) a syringe body with a longitudinal axis, a front end, a connecting piece, disposed at the front end and having a coaxial borehole, and a coaxial cavity; B) an injection piston, which can be shifted coaxially in the cavity; and C) a cannula, which can be connected with the connecting piece, with a central borehole and rear end; wherein D) the front end of the syringe body has a transition segment with a coaxial borehole with constant diameter, connecting the cavity with the borehole in the connecting piece; and wherein E) the borehole in the transition segment and the central borehole have the same cross-sectional area orthogonal to the longitudinal axis at least at the rear end of the cannula; F) the central borehole of the cannula has a constant cross-sectional area q in the axial direction (as seen in Figs below, where the transitional segment has a borehole with a constant diameter that is the same as the bore hole of the connecting piece and see abstract, Col 5 lines 5-40).



Dozier discloses the central borehole of the cannula has a constant cross sectional area q in the axial direction and the cavity of the body has a cross-sectional area Q as shown above, but does not explicitly disclose the ratio of the cross sectional areas $q:Q$ is between 0.2 and 0.033.

However, it is clear that from the Figs that q has a smaller cross sectional area than Q , where it would be obvious that the ration between $q:Q$ can be between 0.2 and .033, where it would have been obvious to one of ordinary skill in the art to modify the size of the components to adjust to different patient's sizes and needs.

Nevertheless, it would also have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the cross sectional areas $q:Q$ to be between 0.2 and 0.033, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

It would also have been an obvious matter of design choice to have the ratio q:Q to be between 0.2 and 0.033, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

5. **Claims 5-10, 13-16** rejected under 35 U.S.C. 103(a) as being unpatentable over Dozier US 4,815,454 as applied to claim 1 above, and further in view of Whitney US 4,220,151.

Dozier discloses the claimed invention as discussed above, where the cannula is connected via threads (as seen above) where it is obvious that it would be a Luer connection since the device dispenses cement and is connected together via threds (see above and see Figs above and abstract) but does not specifically disclose the cannula is connected via a Luer Lock with an internal thread. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the cannula threaded onto the device via an internal thread, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Nevertheless, Whitney discloses a similar device with a luer lock with internal threads between a cannula and the syringe (see Col 2 lines 66-67 - Col 3 lines 1-2).

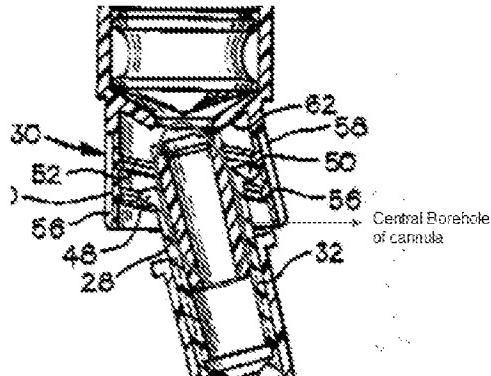
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connection between the cannula and the injection device of Dozier to include reverse the parts, where the cannula is connected to the device via an internal thread as taught by Whitney because the internal threads applies

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a known technique to a known device ready for improvement to yield predictable results of forming a luer lock between a nozzle/cannula and a syringe body (see Col 2 lines 66-67, Col 3 lines 1-2), where it is also a simple substitution of one known element for another to obtain predictable results.

Response to Arguments

6. The drawing objection has been withdrawn.
7. The 112 second paragraph rejections are also withdrawn.
8. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection. The examiner notes that the applicant argues that Whitey does not disclose "a cannula which can be connected with the connecting piece," where Whitey discloses a cannula integral with the syringe body. As clearly shown in Figs 2, 4, and the figure shown in Claim 8 in the previous office action, the cannula with the borehole is detachable from the syringe body as shown below, where the borehole has a constant cross section area q in the axial direction (see Fig above where q is shown, where in the axial direction, dotted line perpendicular to the longitudinal axis, there is a constant cross section area. See also claims 5-7, 10).



With regards to Whitey and the ratio between q:Q, applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Nevertheless, see above where finding the workable ranges would be obvious to one of ordinary skill in the art. The examiner also notes that the ration between q and Q refers to a change of size, where one of ordinary skill in the art would recognize the need to have different sizes to accommodate different patients and patient need. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

*/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733*